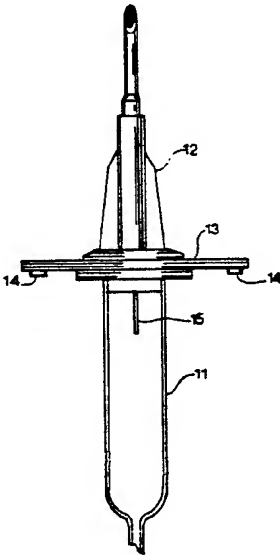
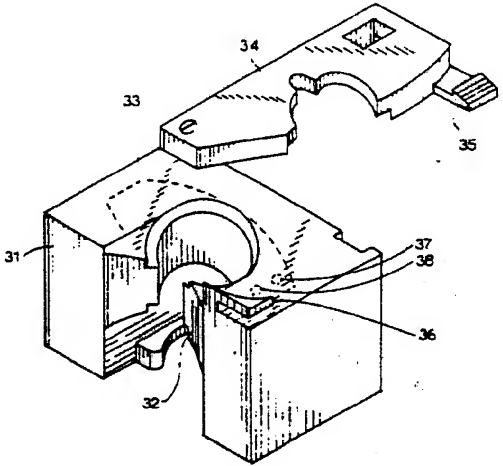




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification⁴ : A61M 5/16	A1	(11) International Publication Number: WO 87/ 07161 (43) International Publication Date: 3 December 1987 (03.12.87)
<p>(21) International Application Number: PCT/US87/01207</p> <p>(22) International Filing Date: 28 May 1987 (28.05.87)</p> <p>(31) Priority Application Number: 868,258</p> <p>(32) Priority Date: 28 May 1986 (28.05.86)</p> <p>(33) Priority Country: US</p> <p>(71)(72) Applicant and Inventor: KAMEN, Dean, L. [US/US]; 44 Gage Road, Bedford, NH 03102 (US).</p> <p>(74) Agents: PIERCE, Kay, H. et al.; One Baxter Parkway, Deerfield, IL 60015 (US).</p> <p>(81) Designated States: AT (European patent), AU, BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent).</p>		<p>Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>
<p>(54) Title: DROP DETECTION HOUSING WITH POSITIVE TACTILE SIGNALING</p> <div style="display: flex; justify-content: space-around; align-items: center;">   </div> <p>(57) Abstract</p> <p>A system is provided for the automatic, self-checking switching of a medical infusion controller among a plurality of modes of operation. A medical infusion controller has a plurality of pressure-sensitive switches (37, 38), each of which corresponds to a different mode of operation. A drip chamber (11) is provided with nub elements (14) in one of a variety of possible configurations each of which correspond to one of the pressure-sensitive switches (37, 38) on the controller. When the drip chamber (11) is placed in the controller, the nub configuration activates the corresponding switch (37, 38). If the controller detects an incorrect number of nubs (14), it delivers an error message.</p>		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FR	France	ML	Mali
AU	Australia	GA	Gabon	MR	Mauritania
BB	Barbados	GB	United Kingdom	MW	Malawi
BE	Belgium	HU	Hungary	NL	Netherlands
BG	Bulgaria	IT	Italy	NO	Norway
BJ	Benin	JP	Japan	RO	Romania
BR	Brazil	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	LI	Liechtenstein	SN	Senegal
CH	Switzerland	LK	Sri Lanka	SU	Soviet Union
CM	Cameroon	LU	Luxembourg	TD	Chad
DE	Germany, Federal Republic of	MC	Monaco	TG	Togo
DK	Denmark	MG	Madagascar	US	United States of America
FI	Finland				

- 1 -

DROP DETECTION HOUSING WITH POSITIVE TACTILE SIGNALING

5

DESCRIPTION

Technical Field

10 The present invention relates to intravenous infusion systems in general and in particular to switching means for setting medical infusion controllers.

Background of the Invention

15 Medical infusion controllers now provide microprocessor control of intravenous fluid delivery rates. These devices include sensors that monitor fluid flow rate and then adjust that rate accordingly. Despite the automatic nature of these devices, they typically must be manually set by
20 the operator to indicate to the microprocessor whether the particular infusion set in use contains a 10 cc or a 60 cc cannula. Thus, there is a potential for serious human error. One prior art device has a protruding spring-loaded retractable pin switch on the controller. 10-cc and 60-cc
25 cannula drip chamber are distinguished by the presence or absence of an aperture to receive the pin. If the aperture is absent, the pin is urged into the retracted position. If the aperture is present, the pin fits into the aperture, and thus does not retract. The two pin positions are
30 associated with two different modes of operation. It can be seen that there is room for error, inasmuch as misalignment or malfunction of the pin can cause incorrect data to be signalled to the controller, by either

- 2 -

retracting even in the presence of an aperture, or by failing to retract even in the absence of an aperture.

Disclosure of Invention

5

The present invention provides a system for automatically switching the controller between the 10 cc cannula setting and the 60 cc cannula setting. Rather than the retractable pin switch in the prior art, the present
10 invention provides a plurality of pressure activated switches on the controller. These switches are configured in such a way that the controller will be set to a desired mode of operation when one and only one switch is activated. When more or less than one switch is activated,
15 the controller will deliver an error message to the user. Drip chambers with different sized cannulae are provided with nubs in one of a variety of configurations designed to set the controller's mode of operation to correspond with that particular drip chamber's cannula size. When the drip
20 chamber is placed in the controller, the nub comes into contact with the appropriate switch and the controller is thereby set to the appropriate mode of operation.

Thus, the present system, which conveys a positive signal to the control based on the presence of a nub in a
25 particular location, avoids the aforementioned potential for error in the prior art device. As discussed above, the controller will send an error message and/or enter into an alarm mode unless an affirmatively correct signal is received. Thus, unlike the prior art device, the present
30 device will not operate if, for example, a drip chamber from another manufacturer is placed in the controller, or if some of the contact sites are misaligned.

35

Brief Description of the Drawings

Fig. 1 shows a side elevational view of one possible embodiment of a drip chamber assembly according to the present invention.

Fig. 2 shows a elevational view from above of the flange element of the drip chamber assembly shown in Fig. 1.

Fig. 3 shows a perspective view from above of one possible medical infusion controller for use with the drip chamber assembly shown in Fig. 1.

Fig. 4 shows a perspective view from above of the drip chamber of Fig. 1 placed in the medical infusion controller of Fig. 3.

Description of Specific Embodiments

Fig. 1 shows one possible embodiment of the present invention. The drip chamber 11 with cannula 15 and spike element 12 is provided with a flange element 13. The flange element is provided with a pair of nubs 14 that are disposed in such a way that whichever side of the flange is presented to a medical infusion controller, the nub on that side of the flange is located in the same relative position.

This will be better understood in Fig. 2, which shows two possible configurations of nubs on the flange element. It will be seen that the nubs are radially symmetric to each other around the center of the drip chamber area 21. Thus, regardless of which end of the flange is up, nub 14a will always be in the righthand corner and nub 14b will always be in the lefthand corner.

Fig. 3 shows a possible medical infusion controller for use in conjunction with the drip chamber shown in Fig. 1. The body 31 of the controller is provided with an aperture 32 for receiving the drip chamber. Surface 33 of the controller receives the flange element. The flange element is held in place by hinged retaining element 33, the end of

- 4 -

which 35 locks into mating element 36. The mode of operation of the controller is set by the actuation of either switch 37 or 38. Although two switches are shown, the invention would apply to any number of switches greater
5 than one.

Using means well known in the art, the controller is designed to enter one of various modes of operation upon the activation of exactly one switch. When more or less than one switch is activated, the controller will deliver
10 an error message to the user. It would be possible as well for the controller to enter an alarm mode.

In the present embodiment, it is contemplated to use the switching system to switch the controller to either a mode of operation appropriate to a 10-cc cannula or to a
15 mode of operation appropriate to a 60-cc cannula. However, it will be clear that the inventive concept is not limited to switching to these two particular modes of operation. The switching system could be modified to include a greater number of nubs in a variety of configurations, thus
20 enabling foolproof switching to one of a potentially large number of mode settings. Further, the modes of operation governed by the switching system are not limited to cannula size. Conceivably, they could include content of the infusion bag, maximum flow rate, model of controller that
25 is expected, characteristics of flow desired for a given class of patient, etc.

Because of the automatic setting of the controller, and the error message delivered upon presentation of an inappropriate nub number or configuration, the present
30 system provides a safety device. It will be readily apparent that the system guards against undesired settings resulting either from human error or from those errors resulting from the use of retractable pin-type switches discussed earlier.

35 Fig. 4 shows the drip chamber of Fig. 1 placed in the controller of Fig. 3. The nub on the side of the flange element over the switches is urged onto the corresponding switch by retaining element 34. As can be seen, it makes

- 5 -

no difference which side of the flange element is over the switches. As discussed above, because of the symmetry of the flange element and the symmetrical configuration of the nubs on the flange element, either side of the flange
5 element causes the activation of the same switch, and thus produces the same setting of the controller's mode of operation.

10

15

20

25

30

35

- 6 -

What is claimed is:

1. An automatic switching system for use with a medical infusion controller, comprising

a drip chamber;

5 a flange affixed to the drip chamber;

at least one tactile signalling nub affixed to the flange in one of a plurality of predetermined alternative positions;

switching means in the controller for switching the
10 controller between a plurality of modes of operation, the switching means being responsive to the presence of a nub in a predetermined position on the flange when the drip chamber is in engagement with the controller, the switching means further sending an error message when any number of
15 nubs other than a preset number of nubs is detected.

2. A system according to claim 1, wherein the flange includes a pair of symmetrically disposed wing members;

the switching means includes means responsive to the
20 presence of a nub in a predetermined position on only one but not both of the wing members at a given time;

the wing members include nubs so disposed that the controller switches to the desired mode of operation independent of which of the two wings is in engagement with
25 the switching means.

3. A drip chamber assembly for use with an automatic switching system in a medical infusion controller, the drip chamber assembly comprising:

a drip chamber;

30 a flange affixed to the drip chamber;

at least one tactile signalling nub affixed to the flange in one of a plurality of predetermined alternative positions.

4. A drip chamber assembly according to claim 3,
35 wherein:

the flange includes a pair of symmetrically disposed wing members; and

the wing members include nubs so disposed that the

- 7 -

desired mode of operation is signaled independent of which of the two wings is used for signaling.

5

10

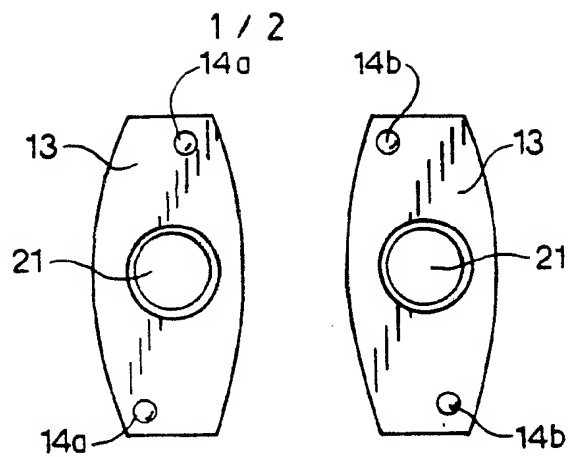
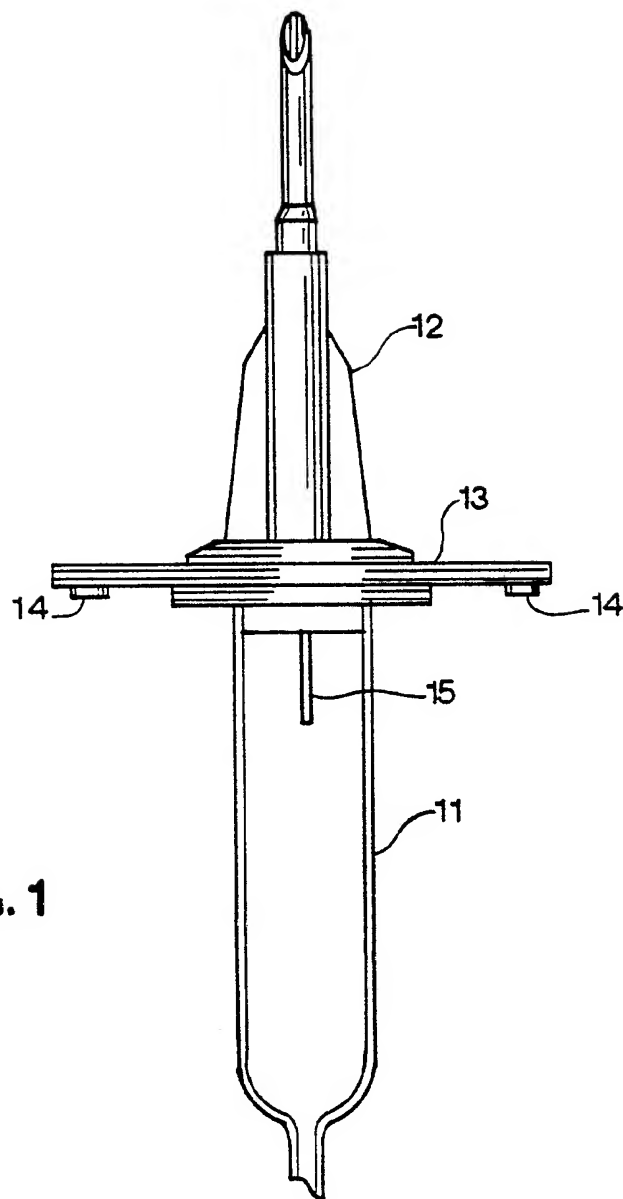
15

20

25

30

35

**FIG. 2****FIG. 1**

2 / 2

FIG. 3

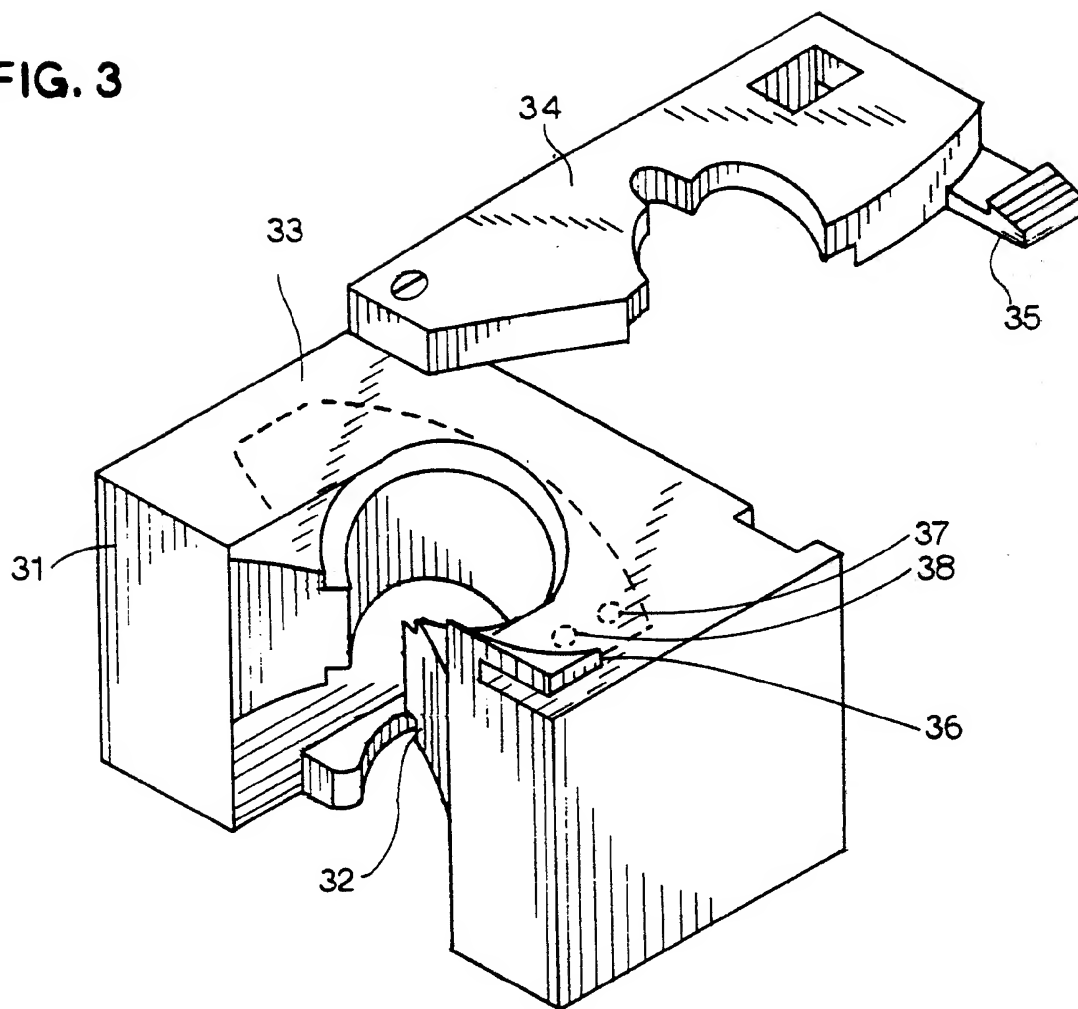
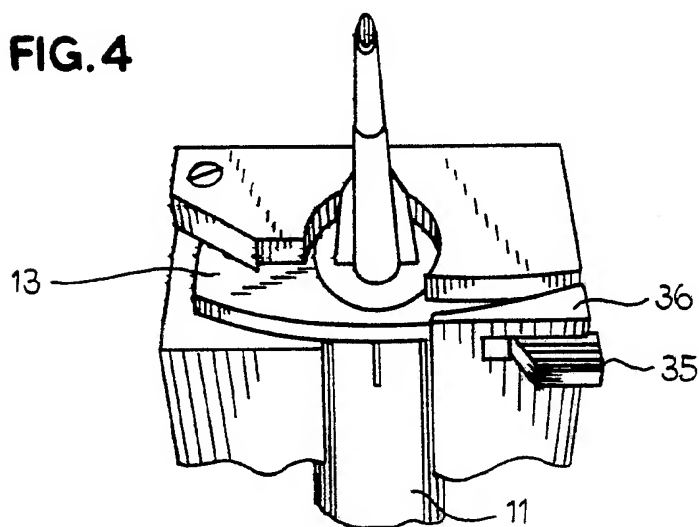


FIG. 4



INTERNATIONAL SEARCH REPORT

International Application No PCT/US87/01207

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ³		
According to International Patent Classification (IPC) or to both National Classification and IPC		
IPC(4) A61M 5/16		
U.S. Cl. 604/251, 67		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁴		
Classification System :	Classification Symbols	
U.S. Cl. 604/251, 253, 254, 255, 246, 65, 67		
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁵		
III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹⁴		
Category *	Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No. ¹⁴
Y	US, A, 4,557,725 (HEYNE ET AL) 10 December 1985, (Note column 4, lines 19-68; and column 5, lines 16-24).	1-4
Y	US, A, 4,321,461 (WALTER, JR. ET AL) 23 March 1982, (note column 2, lines 25-55). See entire document.	1-4
A	US, A, 4,037,597 (FORBERG) 26 July 1977. See entire document.	
A	US, A, 4,346,606 (CANNON ET AL) 31 August 1982. See entire document.	
A	US, A, 4,397,648 (KNUTE) 09 August 1983. See entire document.	
A	US, A, DES 273,419 (D'ALO ET AL) 10 April 1984. See entire document.	
A	US, A, 4,533,350 (DANBY ET AL) 06 August 1985. See entire document.	
A	US, A DES 279,602 (D'ALO ET AL) 09 July 1985. See entire document.	
<p>* Special categories of cited documents: ¹⁵</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search ²	Date of Mailing of this International Search Report ²	
30 September 1986	01 OCT 1987	
International Searching Authority ¹	Signature of Authorized Officer ¹⁸	
ISA/US	Gene B. Kartchner	